

मिसिलस.- 8(29)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(29)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 161/29/2016/F

Proceeding No : 161/29/2016/F

Minutes of the 161st and 29th meeting of Authority under DPCO, 2013 held on 27.4.2016 at 11.00 AM.

- I. 1. The 161st overall meeting of the Authority, which is the 29th under the DPCO, 2013 was held on 27th April, 2016 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-

- (i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
- (ii) Dr. K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Deptt. of Economic Affairs.
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Shri R. Chandrashekar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCGI).

1.1 The following officers of NPPA also attended the meeting and assisted the Authority in its deliberations:-

- (i) Shri Kalyan Nag, Adviser (Cost)
- (ii) Smt. Roshni Sohni, Director (M&E/Admn.)
- (iii) Shri A.K. Khurana, Director (Pricing)
- (iv) Shri A.P.S. Sawhney, Director (Overcharging)
- (v) Shri T.R. Sathishchandran, Asstt. Director (Pricing)
- (vi) Shri Baljit Singh, Asstt. Director (Pricing)

1.2 Chairman, NPPA welcomed all the members present in the meeting.

II. Agenda Items

1. Agenda Item no. 1: Confirmation of Minutes of the 28th Meeting held on 12.4.2016.

As no comments were received on the minutes of 160th and the 28th Meeting under DPCO, 2013, the Authority confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

Noted.

3. Agenda Item no. 3: Fixation of Ceiling Prices of Scheduled formulations in the revised Schedule-I of DPCO, 2013 (NLEM, 2015).

The Authority discussed in detail the data on 56 formulations and approved the ceiling prices in respect of the following 54 formulations. The Authority directed to collect further details of PTR, MAT value and pack size in respect of the remaining two formulations viz. Trastuzumab

injection 440mg/50ml (from M/s Mylan Lab. Ltd.) and Rabies vaccine from the concerned marketing/manufacturing companies.

Sl. No.	NLEM Number	Formulation	Strength	Unit for ceiling price	Ceiling price (Rs.)
Newly Added Formulations					
1	2.1.4	Mefenamic acid	Oral liquid 100 mg/5 ml	Per ML	0.48
2	3.7	Prednisolone	Oral liquid 5mg / 5ml	Per ML	0.40
3	3.7	Prednisolone	Oral liquid 15mg / 5ML	Per ML	0.71
4	5.4	Levetiracetam	Oral liquid 100 mg/ml	Per ML	3.53
5	6.1.1.2	Mebendazole	Oral liquid 100 mg/5 ml	Per ML	0.73
6	6.1.2.1	Diethylcarbamazine	Oral liquid 120 mg/5 ml	Per ML	0.43
7	6.2.1.1	Amoxicillin	Oral liquid 250 mg/5 ml	Per ML	1.26
8	6.2.1.2	Amoxicillin (A) + Clavulanic acid (B)	Dry Syrup 125 mg (A) + 31.25 (B)/5 ml	Per ML	2.00
9	6.2.1.6	Cefadroxil	Oral liquid 125 mg/5 ml	Per ML	0.58
10	6.2.2.3	Clarithromycin	Oral liquid 125mg/5 ml	Per ML	4.01
11	6.2.2.7	Metronidazole	Oral liquid 200 mg/5 ml	Per ML	0.25
12	6.2.2.8	Nitrofurantoin	Oral liquid 25 mg/5 ml	Per ML	0.76
13	8.4.8	Lactulose	Oral liquid 10 g/15 ml	Per ML	0.98
14	8.1.9	Capecitabine	Tablet 500 mg	Per Tablet	117.27
15	8.1.26	Mesna	Injection 100 mg/ml	Per ML	14.93
16	8.1.29	Paclitaxel	Injection 100 mg/16.7 ml	Per ML	207.08
17	8.3.2	Cyclosporine	Oral liquid 100 mg/ml	Per ML	79.43
18	12.3.5	Labetalol	Injection 5 mg/ml	Per ML	47.03
19	14.2.2	Fusidic acid	Cream 2%	Per GM	8.46
20	14.4.1	Benzoyl peroxide	Gel 2.5%	Per GM	3.48
21	14.4.4	Salicylic acid	Ointment 6%	Per GM	1.67
22	19.4	Xylometazoline	Nasal drops 0.1 %	Per ML	4.82
23	19.4	Xylometazoline	Nasal drops 0.05 %	Per ML	3.65
24	20.1.3	Ranitidine	Oral liquid 75 mg/5 ml	Per ML	0.54
25	20.1.4	Sucralfate	Oral liquid 1 g	Per ML	0.66
26	21.1.2	Human chorionic gonadotropin	Injection 1000 IU	Each Pack	189.11
27	21.1.2	Human chorionic gonadotropin	Injection 5000 IU	Each Pack	371.39
28	23.5	Vecuronium	Powder for Injection 10 mg	Each Pack	168.24
29	23.5	Vecuronium	Powder for Injection 4 mg	Each Pack	81.20
30	24.1	Alprostadil	Injection 0.5 mg/ml	Per ML	5254.55
31	24.2	Caffeine	Injection 20 mg/ml	Per ML	232.89
32	25.1.1	Acyclovir	Ointment 3%	Per GM	9.66
33	25.1.5	Natamycin	Drops 5%	Per ML	21.16
34	25.3.1	Proparacaine	Drops 0.5%	Per ML	9.26
35	25.6.1	Hydroxypropyl methylcellulose	Injection 2%	Per ML	34.79
36	25.7.1	Carboxymethylcellulose	Drops 0.5%	Per ML	11.59
37	25.7.1	Carboxymethylcellulose	Drops 1 %	Per ML	13.03
38	26.1.1	Dinoprostone	Gel 0.5 mg	Per Gram	75.21
39	27.1.2	Fluphenazine	Depot Injection 25 mg/ml	Per ML	46.42
40	27.1.4	Risperidone	Oral liquid 1 mg/ml	Per ML	1.78
41	28.1.1	Budesonide	Inhalation (MDI/DPI) 100 mcg/dose	Per MDI	1.22

42	28.1.1	Budesonide	Inhalation (MDI/DPI) 200 mcg/dose	Per MDI	1.50
43	28.1.1	Budesonide	Respiratory Solution 0.5mg/ml	Per ML	9.93
44	28.1.1	Budesonide	Respiratory Solution 1mg/ml	Per ML	11.98
45	28.1.2	Budesonide (A)+ Formoterol (B)	Inhalation (MDI/DPI) 400 mcg (A) + 6 mcg (B)	Per MDI	2.74
46	28.1.2	Budesonide (A)+ Formoterol (B)	Inhalation (MDI/DPI) 200 mcg (A) + 6 mcg (B)	Per MDI	2.19
47	28.1.2	Budesonide (A)+ Formoterol (B)	Inhalation (MDI/DPI) 100 mcg (A) + 6 mcg (B)	Per MDI	1.74
48	28.1.4	Ipratropium	Respirator solution for use in nebulizer 250 mcg/ml	Per ML	2.35
49	29.4	Potassium chloride	Injection 150 mg/ml	Per ML	2.25
50	30.8	Thiamine	Injection 100 mg/ml	Per ML	23.02
Common Formulations					
51	8.1.10	Carboplatin	Injection 10 mg/ml	Per ML	49.38
52	8.1.12	Cisplatin	Injection 1mg / 1ml	Per ML	6.39
53	8.1.29	Paclitaxel	Injection 30mg / 5ml	Per ML	207.08
54	25.2.1	Prednisolone	Drops 1%	Per ML	3.12

4. Agenda Item no. 4: Fixation of retail price in respect of new drugs.

The Authority discussed the cases of retail price fixation of new drugs falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of the following under para 5 of the DPCO 2013, as under:

S. No.	Company name/Product name	Approved Price (Rs.)
4(i)	M/s Nitin Lifescience Ltd. is the Manufacturer and M/s Galpha Lab. Ltd. (marketing company) – Diclofenac Sodium 75mg + Benzyl Alcohol 2% (as preservative) – (New Rhumacort Injection).	14.30/ml
4(ii)	M/s Enicar Pharmaceuticals Pvt. Ltd. (Manufacturer) and M/s Group Pharmaceuticals Ltd., (Marketing company) – Dextromtharphan BHR 10mg + Chlorphenaramine maleate 2mg – (Sudin D+ Syrup).	0.50/ml

5. Agenda Item no. 5: Minutes of the 1st meeting of Committee of Experts held on 19.4.2016 under Para 11(3&4) of DPCO 2013.

The Authority discussed the minutes of the 1st meeting of the Committee of Experts held on 19.4.2016 under Para 11(3&4) of DPCO 2013. With respect to the issue of price fixation of I.V. Fluids or other items where fixation of ceiling price on the basis of pack size is essential and for which there is specific representation for pack-wise price fixation (example of such cases includes I.V. Fluids, Gentamicin Injection, Paracetamol injection, Tetanus toxoid injection, Dexamethasone injection etc.). The Committee discussed that in those cases where price fixation has to be done as per para 11(3) of DPCO, 2013 and wherever review orders are pending with the DOP, price fixation exercise may have to be done with May, 2012 or September 2013 data, as base data. This will require an amendment of the relevant para of DPCO, 2013

6. Agenda Item no. 6: Withdrawal of Price fixation order no. S.O. 1253(E) dated 29.3.2016 (at S. No. 34) regarding Isoniazid tablet 300mg.

Noted and Approved.

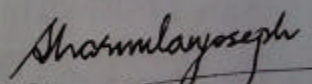
7. Agenda Item no. 7: Overcharging matter of M/s Orbit Life Science Pvt. Ltd. – Applicability of price notification S.O. 2120(E) dated 20.9.2011 in supersession of S.O. 440(E) dated 23.3.2007.

The Authority discussed the matter in detail and decided that legal opinion may be sought from Department of Legal Affairs through DOP.

8. Additional Item discussed:

The Authority discussed the matter related to fixation of ceiling prices in respect of formulations where market based data in the retail channel is not available with NPPA. The Authority decided that suitable amendments to DPCO, 2013 may be proposed for consideration of institutional data in place of Price to Retailer (PTR) data, where PTR is not available, by adding 16% and 8% as retailer margin and wholesaler margin respectively.

9. The meeting ended with vote of thanks to the chair.


(Dr. Sharmila Mary Joseph K)
Member Secretary